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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,783	12/08/2003	L. Dean Parks	1238.009	4821
27353	7590	01/05/2010	EXAMINER	
MELVIN K. SILVERMAN AND ASSOC'S PC			PERREIRA, MELISSA JEAN	
500 WEST CYPRESS CREEK ROAD				
SUITE 350			ART UNIT	PAPER NUMBER
FT. LAUDERDALE, FL 33309			1618	
			MAIL DATE	DELIVERY MODE
			01/05/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/730,783	PARKS, L. DEAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 December 2009.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-16 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 11-16 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/16/09 has been entered.

### ***Claims and Previous Rejections Status***

2. Claims 11-16 are pending in the application.

3. The rejection of claims 11-16 under 35 U.S.C. 103(a) as being unpatentable over Pearlman et al. (WO/9918800) in view of Huet et al. (US 6,426,333B1) is withdrawn.

### ***New Grounds of Rejection Necessitated by the Amendment***

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pearlman et al. (WO/9918800).

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6. Pearlman et al. (WO/9918800) discloses a topical composition comprising a pediculocide (i.e. ivermectin) with a pediculostatic agent (i.e. CETAPHIL ® cleanser) (abstract; p18, lines 14-16; p19, lines 19-28). The levels of active ingredient (i.e. ivermectin) may be from about 0.25% to about 2.5%.

7. Pearlman et al. further teaches that any commercially available product, such as cleansers, lotions, moisturizers, etc. may be used as the pediculostatic agent, not excluding Cetaphil ® moisturizing lotion (Pearlman et al., p17, lines 1-10). The pediculostatic agent is used for the immobilization of the lice (abstract; p3, lines 33+ to p4, lines 1-10).

8. Pearlman et al. does not explicitly disclose Cetaphil ® moisturizing lotion as the pediculocide or explicitly disclose the concentration of ivermectin from about 0.05 to about 0.1% or 0.075% (w/v).

9. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the Cetaphil ® moisturizing lotion for the Cetaphil ® Cleanser as both products are produced by the same laboratories (Galderma Laboratories, Inc.) and Pearlman et al. teaches of the use of cleansers and lotions/moisturizers interchangeably as a pediculostatic agent.

10. Also, at the time of the invention it would have been obvious to one ordinarily skilled in the art to include an active agent (i.e. ivermectin) in a concentration of from about 0.1%, etc. in combination with a CETAPHIL ® cleanser or CETAPHIL ® moisturizer as Pearlman et al. teaches of the concentration of from about 0.25% to about 2.5% where the concentration of from about 0.25% of Pearlman et al.

encompasses the concentration of the instant claims of from about 0.1% and from about 0.075%.

11. The intended use of the dermatological composition is not afforded any patentable weight. “The recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). The topical compositions of the combined disclosures encompass the formulation of the instant claims and thus are capable of the same functions (i.e. treating transient acantholytic dermatitis, acne millaris necrotica, etc.) and have the same properties as the dermatological composition of the instant claims.

### ***Response to Arguments***

12. Applicant's arguments filed 12/16/09 have been fully considered but they are not persuasive.

13. Applicant asserts that the instant composition does not contain parabens and that Pearlman et al. teaches away from the present invention because it teaches using Cetaphil ® cleanser which contains three parabens.

14. Pearlman et al. teaches of a topical composition comprising a pediculocide (i.e. ivermectin) with a pediculostatic agent/immobilizing agent (i.e. CETAPHIL ® cleanser) but further teaches that any commercially available product, such as cleansers, lotions, moisturizers, etc. may be used as the pediculostatic agent/immobilizing agent, not excluding Cetaphil ® moisturizing lotion (Pearlman et al., p17, lines 1-10). Therefore, it would have been obvious to one skilled in the art to substitute the Cetaphil ®

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moisturizing lotion for the Cetaphil ® Cleanser as both products are produced by the same laboratories (Galderma Laboratories, Inc.) and Pearlman et al. teaches of the use of cleansers and lotions/moisturizers interchangeably as a pediculostatic agent/immobilizing agent.

15. Applicant asserts that Pearlman et al. specifically teaches that the pediculocides active ingredients can be used at levels effective to achieve their intended results of treating head lice infestations, which are at a concentration from about 0.25% to about 2.5%. Therefore, contrary to the instant composition, Pearlman et al's method requires a substantially higher ivermectin concentration in order to be effective to treat head lice infestations. It should be noted that the lowest concentration of ivermectin in Pearlman et al's composition is more than double of the highest concentration in the instant composition.

16. The concentration of ivermectin of Pearlman et al. is from about 0.25% which does not exclude of from about 0.1% of the instant claims. The recitation of from about 0.1% of the instant claims is broad and thus the range of Pearlman et al. overlaps the range of the instant claims. A *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75%

nickel, 0.25% molybdenum, balance titanium and *0.94% nickel*, 0.31% molybdenum, balance titanium.).

17. The assertions with regard to the reference of Huet et al. are moot due to the new grounds of rejection.

### ***Conclusion***

18. No claims are allowed at this time.

19. This is a continuation of applicant's earlier Application No. 10/730,783. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/  
Examiner, Art Unit 1618